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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,290	03/30/2004	David Milton Hadley	330498004US	8336
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PERKINS COIE LLP PATENT-SEA P.O. BOX 1247 SEATTLE, WA 98111-1247			EXAMINER GEDEON, BRIAN T	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/815,290

Applicant(s)

HADLEY ET AL.

Examiner

Brian T. Gedeon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/20/04 & 8/11/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 10 and 12 –19, in particular 10 and 12, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is insufficient enablement in the specification with regards to the use of “frames”.

Claims 13-19 are rejected since they depend from rejected claim 12.

2. Claims 21-30, in particular claim 21, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not sufficiently set forth of how to “ascertain a reference waveform from the preliminary alternan waveform” and how to “determine a final waveform based on the preliminary alternan waveform and the reference waveform”.

Claims 22-30 are rejected since they depend on rejected base claim 21.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular regards to claims 1, 11, and 21, it is indefinite as to the meaning of the "relative time intervals." Do they refer to the duration of the T-wave, or the time between successive T-wave? Please clarify.

In regards to claims 5 and 16, it is indefinite as to what "statistically insignificant data" is "highly color contrasted" with.

Claims 2-4, 6-10, 12-15, 17-20, and 22-30 are also rejected since they depend from the rejected base claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 9, 11, and 20 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Verrier et al. (US Patent no. 5,148,812).

In regards to claims 1 and 11, Verrier et al. discloses a non-invasive method of tracking cardiac vulnerability by analysis of T-wave alternans by means of a alternans monitoring unit 400 including ECG sensing leads 401. The heart is monitored to sense the ECG signal and the location of the T-wave is estimated, col 4 lines 1 and 3-5. Each T-wave is partitioned into a plurality of time divisions (step 310, fig. 3) and formed into a time series (step 314, fig. 3), col 4 lines 6-11, and the alternation amplitude for each time series is then estimated (step 318, fig. 3). The Examiner interprets the "location of the T-Wave" mentioned in Verrier et al. to be the "T-wave segment" recited in the application. The "time series" mentioned in Verrier et al. is interpreted by the Examiner to be the "time intervals of T-wave segments" recited in the application. Figure 15b of Verrier et al. shows superimposed ECG waveforms including the T-wave portion; the superimposition of waveforms would inherently mean that there is a "plurality" of segments obtained. A color monitor 718 is used to display a menu-driven program which has features to graphically display the ECG waveforms, the time series data for each T-wave, or the actual alternans estimate data, col 12 lines 29-35; the menu-driven program also stores standard T-wave alternans values used for data comparison, col 12 lines 19-21. Regarding claim 11, which substantially claims the same limitations of claim 1, the physiological signal is measured by plurality of ECG leads 401 which are

monitored by a 16 channel system, col 12 lines 6-7. Therefore it would be obvious if not inherent to one of ordinary skill in the art at the time the invention was made that T-wave alternans values can be measured and partitioned in a time series and graphically displayed.

In regards to claim 2, Verrier et al. states that the "dynamic estimation" is performed on the "time series" to estimate the amplitude of alternation, col 4 lines 14-16. Figures 11a-c show surface plots of the T-wave with amplitude of the alternans ("alternans level") on one axis and time on another. Further, color monitor 718 is used to graphically display a menu-driven program which has features to display the ECG waveforms, the time series data for each T-wave, or the actual alternans estimate data, col 12 lines 29-35.

In regards to claim 3, Verrier et al. states that the "dynamic estimation" is performed on the "time series" to estimate the amplitude of alternation, col 4 lines 14-16. Figures 11a-c show surface plots of the T-wave with amplitude of the alternans ("alternans level") on one axis and time on another.

In regards to claims 9 and 20, color monitor 718 is used to graphically display a menu-driven program, which has features to display the ECG waveforms, the time series data for each T-wave, or the actual alternans estimate data, col 12 lines 29-35.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4, 7, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al. (US Patent no. 5,148,812) in view of Warner et al. (US Patent no. 6,409,659).

In regards to claim 4, 7, 15 and 18, Verrier et al. substantially describes the invention as claimed except the color coding of relative amplitudes of the T-wave alternans. Warner et al. describes a sensor 18 for acquiring physiological data and assigning a color according to the amplitude of a data point and plots the point on a display monitor 12, col 2 lines 5-10. Figure 3 shows that the displayed waveforms are plotted against time. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Verrier et al. in view of Warner et al. in order to display amplitudes of physiological patient data using a color coordinated display.

6. Claims 5, 6, 8, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al. (US Patent no. 5,148,812) in view of Warner et al. (US Patent no. 6,409,659) and further in view of Gleeson (US Patent no. 6,741,887).

In regards to claims 5 and 16, Verrier et al. in view of Warner et al. describes the invention substantially as claimed except assigning "highly contrasted color" to the values categorized as being statistically insignificant. Gleeson describes color shading is applied to a sample of data in which the baseline values are assigned a particular

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color, deviations from that baseline value are represented with changes in color intensity of the baseline color, with the greatest deviations from baseline having the greatest color intensity, col 5 lines 5-15. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the color contrast/intensity to indicate areas of interest or disinterest in the collected data set.

In regards to claims 6, 8, 17 and 19, Verrier et al. substantially describes the invention as claimed except the assignment of white to a certain amplitude value of a T-wave alternan. Warner et al. method allows a user to select any color to represent a given amplitude, and alternatively the monitoring system 10 is programmed to provide the user with a set of manufacturer defined color schemes, col 3 lines 42-45. Further, Gleeson describes a method and apparatus for presenting periodic data, in particular a physiological data, col lines 5-10. Areas of specific interest are rendered color as a function of amplitude; areas surrounding the area of interest are rendered a neutral color regardless of its actual amplitude, col 5 lines 57-65 – col 6 lines 1-4. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to assign a neutral color or a color such as “white” to areas not of particular interest, specifically to an amplitude of a “T-wave alternan less than a standard deviation for the T-wave alternan values.”

7. Claims 10 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al. (US Patent no. 5,148,812) in view of Nearing et al. (US Patent no. 6,169,919).

In regards to claims 10 and 12, Verrier et al. describes the invention as claimed by storing T-wave time series data in bins, thereby effectively separating segments that can be scrolled independently of each other that which can be viewed with the menu-driven program which can be viewed on color monitor 718, col 12 lines 29-35. Nearing et al. teaches that T-wave alternans can be evaluated in patients undergoing a stress test, col 13 lines 5-10 and 19-22. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to collect T-wave alternan data from patients undergoing stress tests and to separately store time series of T-wave data in a plurality of bins or "frames" in order to independently view a representation the separate segments contained therein.

In regards to claim 13, Verrier et al. states that the "dynamic estimation" is performed on the "time series" to estimate the amplitude of alternation, col 4 lines 14-16. Figures 11a-c show surface plots of the T-wave with amplitude of the alternans ("alternans level") on one axis and time on another. Further, color monitor 718 is used to graphically display a menu-driven program which has features to display the ECG waveforms, the time series data for each T-wave, or the actual alternans estimate data, col 12 lines 29-35.

In regards to claim 14, Verrier et al. states that the "dynamic estimation" is performed on the "time series" to estimate the amplitude of alternation, col 4 lines 14-16. Figures 11a-c show surface plots of the T-wave with amplitude of the alternans ("alternans level") on one axis and time on another.

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8. Claims 21-23 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al. (US Patent no 5,148,812) in view of Arnold et al. (US Patent no. 5,713,367).

In regards to claim 21, Verrier et al. substantially describes the invention as claimed except for the determination of T-wave alternan values at relative time intervals from repeating waveforms representative of a heartbeat. Arnold et al. describes a scheme for measuring alternan from a physiologic signal including a sequence of substantially repeating waveforms, the method comprising the steps of: receiving a physiologic signal representative of activity of the heart, and digitally processing the physiologic signal to determine a level of alternans in the signal, col 2 lines 44-54. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to assess alternan levels from the mathematical processing of waveforms representative of a heartbeat.

In regards to claims 22 and 23, Verrier et al. states that the "dynamic estimation" is performed on the "time series" to estimate the amplitude of alternation, col 4 lines 14-16. Figures 11a-c show surface plots of the T-wave with amplitude of the alternans ("alternans level") on one axis and time on another. Further, color monitor 718 is used to graphically display a menu-driven program which has features to display the ECG waveforms, the time series data for each T-wave, or the actual alternans estimate data, col 12 lines 29-35.

In regards to claim 29, color monitor 718 is used to graphically display a menu-driven program, which has features to display the ECG waveforms, the time series data for each T-wave, or the actual alternans estimate data, col 12 lines 29-35.

9. Claims 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al. (US Patent no 5,148,812) in view of Arnold et al. (US Patent no. 5,713,367) and further in view of Warner et al. (US Patent no. 6,409,659).

In regards to claims 24 and 27, Verrier et al. and Arnold et al. substantially describes the invention as claimed except the color coding of relative amplitudes of the T-wave alternans. Warner et al. describes a sensor 18 for acquiring physiological data and assigning a color according to the amplitude of a data point and plots the point on a display monitor 12, col 2 lines 5-10. Figure 3 shows that the displayed waveforms are plotted against time. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Verrier et al. in view of Warner et al. in order to display amplitudes of physiological patient data using a color coordinated display.

10. Claims 25, 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al. (US Patent no 5,148,812) in view of Arnold et al. (US Patent no. 5,713,367) and further in view of Warner et al. (US Patent no. 6,409,659) and Gleeson (US Patent no. 6,741,887).

In regards to claim 25, Verrier et al. in view Arnold et al. and Warner et al. describes the invention substantially as claimed except assigning "highly contrasted color" to the values categorized as being statistically insignificant. Gleeson describes

color shading is applied to a sample of data in which the baseline values are assigned a particular color, deviations from that baseline value are represented with changes in color intensity of the baseline color, with the greatest deviations from baseline having the greatest color intensity, col 5 lines 5-15. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the color contrast/intensity to indicate areas of interest or disinterest in the collected data set.

In regards to claims 26 and 28, Verrier et al. in view Arnold et al. and Warner et al. describe the invention substantially as claimed except the assignment of white to a certain amplitude value of a T-wave alternan. Warner et al. method allows a user to select any color to represent a given amplitude, and alternatively the monitoring system 10 is programmed to provide the user with a set of manufacturer defined color schemes, col 3 lines 42-45. Further, Gleeson describes a method and apparatus for presenting periodic data, in particular a physiological data, col lines 5-10. Areas of specific interest are rendered color as a function of amplitude; areas surrounding the area of interest are rendered a neutral color regardless of its actual amplitude, col 5 lines 57-65 – col 6 lines 1-4. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to assign a neutral color or a color such as “white” to areas not of particular interest, specifically to an amplitude of a “T-wave alternan less than a standard deviation for the T-wave alternan values.”

11. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Verrier et al. (US Patent no 5,148,812) in view of Arnold et al. (US Patent no. 5,713,367) and Nearing et al. (US Patent no. 6,169,919).

Verrier et al. and Arnold et al. describes the invention as claimed by storing T-wave time series data in bins, thereby effectively separating segments that can be scrolled independently of each other that which can be viewed with the menu-driven program which can be viewed on color monitor 718, col 12 lines 29-35. Nearing et al. teaches that T-wave alternans can be evaluated in patients undergoing a stress test, col 13 lines 5-10 and 19-22. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to collect T-wave alternan data from patients undergoing stress tests and to separately store time series of T-wave data in a plurality of bins or "frames" in order to independently view a representation the separate segments contained therein.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Galen et al. (US Patent no. 6,453,191) discloses a method of color-coding an ECG signal. Guerro et al. (US Patent no. 6,370,423) discloses a method for analysis of biological voltage signals, which includes utilizing a color scheme. Olsen (US Patent no. 5,803,084) shows three dimensional vector cardiographic display and method for displaying the same, which includes color-coding events of the QRS cycle.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272 3447. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272 6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E Pezzuto
Supervisory Patent Examiner
Art Unit 3766

BTG